

# **Exhibit 3**

Highly Confidential - Subject to Further Confidentiality Review

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IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

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IN RE: NATIONAL PRESCRIPTION MDL No. 2804  
OPIATE LITIGATION,

Case No. 17-MD-2804

This document relates to:

All Cases

Hon. Dan A. Polster

-----X

\* \* HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER \* \*

\* \* CONFIDENTIALITY REVIEW \* \*

VIDEOTAPED DEPOSITION

OF

THOMAS P. NAPOLI

New York, New York

Thursday, January 17, 2019

Reported by:

ANNETTE ARLEQUIN, CCR, RPR, CRR, RSA

1           inquiring about that?

2           A.       I don't recall.

3           Q.       As you made the reduced quota demand  
4       for the --

5           A.       Well, I mean, obviously if we're  
6       making a quota request or if we're not due for a  
7       quota request is because of diminished sales.

8           Q.       Do you remember what the reason for  
9       the diminished sales were?

10          A.       That, I don't know.

11          Q.       All right.

12                 MR. LUXTON: Before we go to the next  
13       document, can we take a quick bathroom  
14       break?

15                 MR. EGLER: Sure.

16                 THE VIDEOGRAPHER: The time is  
17       2:37 p.m. We are going off the record.

18                 (Recess is taken.)

19                 THE VIDEOGRAPHER: We are back on the  
20       record at approximately 3:05 p.m.

21                 (Napoli Exhibit 15, Watson document  
22       entitled SOMS Project Evolution IT  
23       Governance Meeting, Bates-stamped  
24       ALLERGAN\_MDL\_02468983 through 68994, marked

1                   for identification, as of this date.)

2           BY MR. EGLER:

3           Q.     Mr. Napoli, you understand you are  
4           still under oath?

5           A.     Yes.

6           Q.     Could you look at what I've just  
7           marked as Exhibit 15?

8                   And as with other documents I've  
9           handed you today, the first page has no Bates  
10          number, but starting on the second page, the  
11          Bates numbers are ALLERGAN\_MDL\_02468983 through  
12          68994.

13                   Can you take a look at this document,  
14          and when you're ready, tell me if you recognize  
15          it.

16                   (Document review.)

17          A.     I do.

18          Q.     What is this document?

19          A.     It's a document I guess detailing the  
20          anatomy of our SOMS project.

21          Q.     So as you think about this document,  
22          that is Exhibit 15, were you responsible for it  
23          or somebody in your group responsible for  
24          creating it?

1 A. For this document itself?

2 Q. This particular document.

3 A. I don't have an exact recollection.  
4 I could have contributed to this.

5 Q. All right. So as you look at this  
6 document, do you have an understanding of who  
7 this presentation was made to?

8 A. Based on the fact that it's an IT  
9 governance meeting, I'm thinking perhaps some --  
10 our IT folks.

11 Q. Have you ever heard that term "IT  
12 governance" in the course of your work at  
13 Watson?

14 A. I have.

15 Q. What does that term mean to you?

16 A. Well, from a governance perspective,  
17 I would think, and it's IT, I would think that  
18 ensuring that any systems or IT-related programs  
19 that we're utilizing within the organization  
20 meet the requirements in compliance with our  
21 standard operating procedures.

22 Q. When you think of an IT department at  
23 Watson while you were there around this time,  
24 April 2012, do you think of one or a couple of

1 particular people that stand out in your mind?

2 A. Not really.

3 Q. So going into this document, on the  
4 fourth page, it's 8984. At the top of the page  
5 it states, "Regulatory Requirement.

6 A. Um-hmm.

7 Q. And it states -- it has the language  
8 of that 21 CFR 1301.74 (B), right?

9 A. Yes.

10 Q. And you see that?

11 So I'll just read it in the record.

12 "The registrant shall design and  
13 operate a system to disclose to the registrant  
14 suspicious orders of controlled substances. The  
15 registrant shall inform the field division of  
16 the administration in his area of suspicious  
17 orders when discovered by the registrant.  
18 Suspicious orders include orders of unusual  
19 size, orders deviating substantially from a  
20 normal pattern, and orders of unusual  
21 frequency."

22 Do you see that?

23 A. Yes, sir.

24 Q. And then the next one says, "Further

1 guidance, December letter of 2000." It states,  
2 "Registrants that rely on rigid formulas to  
3 define whether an order is suspicious may be  
4 failing to detect suspicious orders. For  
5 example, a system that identifies orders as  
6 suspicious only if the total number exceeds the  
7 previous month by a certain percentage or more  
8 is insufficient."

9 Do you see that there?

10 A. Yes.

11 Q. That second group of, or that second  
12 paragraph that I read, do you recognize that as  
13 being from the letter authorized by  
14 Mr. Rannazzisi?

15 A. Yes.

16 Q. And do you remember whether, in that  
17 same letter, Mr. Rannazzisi highlighted the term  
18 "include" in the 21 CFR 1301.74 (B) language  
19 above, that suspicious orders "include" orders  
20 of unusual size, orders deviating substantially  
21 from a normal pattern, and orders of unusual  
22 frequency?

23 A. I don't recall if that was within the  
24 letter.

1           Q.     And that there may be more than those  
2     three requirements or conditions for something  
3     to be a suspicious order?

4           A.     I don't recall if it was in the  
5     letter.

6           Q.     All right. So moving down into this,  
7     on the next page, page 8985, it states, "Current  
8     automated model," and it has various texts  
9     there.

10                   Can you read that text to yourself  
11     and tell me what, in your opinion, it describes?

12                   As you're reading it to yourself,  
13     I'll read it into the record.

14                   "Current automated model designed and  
15     implemented within SAP, primary user is customer  
16     relations," then, dash, "order intake process."

17                   And then it states, "Based on a  
18     'threshold,'" and then, dash, "customer  
19     groupings," and then a bullet point, "class of  
20     trade," and then three dashes underneath there,  
21     "wholesaler, retail chain, distributor,  
22     mail-order, et cetera," then another dash,  
23     "monthly average based on 12" -- "based on  
24     rolling 12-month period," and then "multiplied



1 by static multiplier equals monthly allowable."

2 So as you think about that whole page  
3 together, does that describe the Watson  
4 Suspicious Order Monitoring System around this  
5 time April of 2012?

6 MR. KNAPP: Objection to form.

7 A. It describes a component of the  
8 system.

9 Q. Okay. Then it has that term that we  
10 talked about earlier, "class of trade."

11 Do you see that there?

12 A. Yes.

13 Q. Class of trade, it then says,  
14 "wholesaler, retail chain, distributor, mail  
15 order, et cetera."

16 Is that what you understand a class  
17 of trade to be?

18 A. Yes.

19 Q. All right. How about the next  
20 language that's down there, "monthly average  
21 based on rolling 12-month period," is that class  
22 of trade?

23 A. No.

24 Q. Okay. Why would that be listed there

1 under "class of trade"?

2 Could it be just a mistake --

3 A. Yes.

4 Q. All right. And if you were tabbing  
5 it today, putting it under a bullet point or a  
6 dash, where would you put it? Would you put it  
7 as the same as based on a threshold, customer  
8 groupings, or somewhere else?

9 A. I may put it under a bullet of  
10 formula.

11 Q. Okay. And then the next one,  
12 "multiplied by static multiplier equal monthly  
13 allowable," would you put that under the same  
14 formula bullet?

15 A. Yes.

16 Q. So if you can turn to that next page,  
17 8986, it states "Customer groupings."

18 Do you see that there?

19 A. Yes.

20 Q. And it states, "Individual customer  
21 ship to location monthly average based on 12" --  
22 no, "monthly average based on rolling 12-month  
23 period," and then "multiplied by static  
24 multiplier equal monthly allowable."

1                   It seems to be similar language to  
2           the prior one?

3           A.       Yes.

4           Q.       What does that "customer groupings"  
5           mean?

6           A.       Not having authored this document, I  
7           don't know. I don't want to speculate.

8           Q.       And then it states, "Order pending."  
9           And then the next bullet point is, "Multiplier  
10          table is populated manually based on  
11          estimation."

12                   Do you have an understanding of what  
13          that sentence means?

14          A.       I believe it indicates that the  
15          multiplier is set manually based on a review of  
16          the -- what the normal behavior could be  
17          estimated to be with a customer.

18          Q.       Now as you think about your time at  
19          Watson and Actavis, do you remember about this  
20          time, April 2012, who would have set the  
21          multiplier that's referred to in this page 8986?

22          A.       Setting the multiplier was the  
23          responsibility of my group.

24          Q.       Do you remember if there was one

1 person in particular who would have set the  
2 multiplier?

3 A. I would have authorized it.

4 Q. So with regard to setting the  
5 multiplier, as you think about it, would the  
6 multiplier be the same for every order by a  
7 particular customer or would they differ with  
8 regard to different orders by customers or  
9 something else?

10 A. It would be the same for each  
11 customer.

12 Q. So, say, McKesson was one of the  
13 customers, every multiplier -- let me start  
14 over.

15 Say McKesson was one of the  
16 customers, the multiplier for every order by  
17 McKesson would be the same; is that right?

18 A. Right.

19 Q. So going down further into the  
20 document, "Current Automated System Evaluation"  
21 down below, it says "Based on compliance  
22 concerns."

23 Do you remember there being concerns  
24 about whether Watson's Suspicious Order

1 Monitoring System complied with the DEA  
2 regulations and laws in April 2012?

3 A. I don't recall any specific  
4 compliance concerns, but only our desire to  
5 enhance the system.

6 Q. Okay. Do you remember ever -- anyone  
7 ever telling you that they had concerns about  
8 Watson's Suspicious Order Monitoring System  
9 complying with the DEA regulations and laws  
10 around this time?

11 A. Not that I recall.

12 Q. All right. And then it says below,  
13 "Increased enforcement action by DEA in the area  
14 of SOM audits."

15 And then, "Most recently Cardinal and  
16 CVS failing to maintain systems to detect  
17 diversion."

18 Do you see that there?

19 A. Yes.

20 Q. Do you remember that around this time  
21 that Cardinal Lakeland Distribution Center being  
22 shut down?

23 A. I don't have a specific memory, but I  
24 do know that they had a distribution center that

1           was, I don't know if it was completely shut down  
2           or if there is was a temporary order. I'm not  
3           sure.

4           Q.     And I guess "shut down" isn't the  
5           right way to say it.

6                     They were unable to sell controlled  
7           substances; is that right?

8           A.     Correct.

9           Q.     Okay. So the next bullet point down  
10          states, "Expectation that we know our customers'  
11          customers."

12                    Do you see that there?

13          A.     Um-hmm.

14          Q.     Do you remember where that language  
15          came from, "expectation that we know our," that  
16          we, quote, "know our customers' customers,"  
17          unquote?

18          A.     I don't.

19          Q.     It states, "Cross-functional team  
20          established in 2010."

21                    And I think we talked about that  
22          before, right?

23          A.     Right.

24          Q.     And as you understand it, the

1 cross-functional team that's referred to there  
2 is the group from customer service and the group  
3 from the DEA affairs; is that right?

4 A. That's correct.

5 Q. Oh, and below, it says, "Security and  
6 DEA affairs, IT and customer relations."

7 And the IT component is programming  
8 the automated system into the SAP process; is  
9 that right?

10 A. Right. Or from a project management  
11 standpoint of implementing a new -- if we went  
12 with a new algorithm into the system.

13 Q. And then "Establish goals, compliance  
14 and efficiency."

15 And, again, do you remember there  
16 being a discussion about compliance around this  
17 time frame?

18 A. No, I do not.

19 Q. All right. And then the next one is,  
20 "Budgeted for third-party evaluation in 2011."

21 A. Right.

22 Q. And then turning to the next page,  
23 "Automated System Evaluation," it starts talking  
24 about Cegedim-Dendrite; is that right?

1 A. Yes.

2 Q. And is that the evaluation that we  
3 were talking about in the exhibit before we took  
4 the break?

5 A. Correct.

6 Q. So the next page is "Findings."

7 Do you see that there?

8 (Document review.)

9 A. Yes.

10 Q. So it states -- as you see that word  
11 "Findings," can you -- do you have an  
12 understanding what that means in the context of  
13 this document?

14 A. These would be observations that were  
15 made by the consultant.

16 Q. And the consultant was Buzzeo?

17 A. Yes.

18 Q. And it says, "Use of multiplier to  
19 create monthly threshold."

20 And it says, "Not consistent with  
21 specific requirements noted within regulations  
22 and guidance, and current system will detect a  
23 certain percentage of suspicious orders but not  
24 all."



1 Do you see that there?

2 A. I do.

3 Q. Do you remember that being a finding  
4 that the Buzzeo group made about the Watson  
5 system in early 2012?

6 A. I don't have a specific recollection.

7 Q. Do you remember -- and, you know, I  
8 put a date limitation on that.

9 Is your lack of specific recollection  
10 based on the date or something else?

11 A. It's just... it's been a while.

12 Q. And then it states, "Current model  
13 evaluates at SKU level."

14 Is that pronounced typically "skew"?

15 A. Yes.

16 Q. All right. What is a SKU?

17 A. A SKU is just one, one product. So  
18 it can be oxycodone 10325, 100 fill count, SKU.

19 Q. Do you recognize the difference  
20 between a SKU and an NDC code?

21 A. The SKU could be -- yeah, there,  
22 there is a difference between the two. I don't  
23 know the exact -- SKU is more of a -- we're kind  
24 of exceeding my, probably my area of expertise,

1 but they're both unique identifiers.

2 I think what this is saying here is  
3 that by looking at it at the SKU level, we're  
4 not looking at the total molecule. And that was  
5 an enhancement. So that's something where we  
6 could have enhanced.

7 Q. All right. So it states, "Current  
8 model evaluates at SKU level. Possibility of  
9 distributing orders across multiple SKUs without  
10 detection."

11 So that's where you're talking about  
12 it can be the same, as you refer to it, molecule  
13 but with different SKUs?

14 A. Right.

15 Q. And then the next one is, "System  
16 does not evaluate listed chemicals"?

17 A. Right.

18 Q. I think we talked about that earlier  
19 as well?

20 A. Right.

21 Q. Those are the precursor chemicals  
22 that you talked about?

23 A. Right.

24 Q. And then on the next page, 990, it

1 states, "Revisit approach to SOM to fully  
2 address specific regulatory requirements."

3 And then it states, "Develop SOM that  
4 is a 'non-threshold-based adaptive' -- I'm  
5 sorry, let me read it.

6 "Develop SOM that is a,  
7 'non-threshold-based adaptive,' system trained  
8 to identify suspicious orders by utilizing a set  
9 of historic markers to include," and then  
10 another bullet point, "statistical scoring of  
11 active ingredient order volume versus history,  
12 active ingredient order versus short and  
13 long-term trend, identification of high/low  
14 frequency ordering behavior."

15 And then the next bullet point is  
16 "Base system on milligram strength rather than  
17 SKU."

18 A. Um-hmm.

19 Q. And then, "Include list of chemical  
20 within system."

21 And then, "Based on recommendations,  
22 GS and DEAA requested a proposal and quote."

23 In the context of this document, do  
24 you know what GS and DEAA would be?

1 A. Global security and DEA affairs.

2 Q. And your group was DEA affairs; is  
3 that right?

4 A. Yes.

5 Q. And then the next dash is "Establish  
6 meeting with IT and consultant."

7 A. Um-hmm.

8 Q. "Understand scope, confirm that  
9 solution was appropriate and achievable." And  
10 then the next one is "Budgeted for 2012  
11 implementation."

12 Do you see that there?

13 A. Yes.

14 Q. Do you remember the -- do you  
15 remember whether there was a decision around  
16 this time, April 2012, to implement the Buzzeo  
17 system at Watson?

18 A. Yes, I believe there was.

19 Q. All right. Do you remember who made  
20 that decision?

21 A. It would have been my management.

22 Q. Did you support the conclusion to  
23 implement the Buzzeo system?

24 A. I definitely supported enhancing our

1       system. You know, the automated system that  
2       we're talking about is -- we are talking about  
3       just one component within the system, that's  
4       what I want to make clear. So we're not relying  
5       on one component of a system as our Suspicious  
6       Order Monitoring program.

7           Q.     And as you had been talking about  
8       earlier, in addition to this process, there is  
9       the onboarding process and reviews; is that  
10      right?

11           A.     The Know Your Customer due diligence.

12           Q.     And Know Your Customer due diligence.  
13                   And then beyond the automated system,  
14       there is a process of customer service clearing  
15       and then, if necessary, DEA affairs clearing of  
16       orders; is that right?

17           A.     Yes, sir.

18           Q.     And if none of those processes work,  
19       the order will be reported to the DEA as  
20       suspicious; is that right?

21           A.     Correct.

22           Q.     All right.

23                   All right. You can set this aside.

24           A.     Okay.